



*The HIV Incidence Study (HIVIS)*  
**Public Health—Seattle & King County**  
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Seattle, WA 98104

**Serologic Testing Algorithm for Recent HIV Seroconversions (STARHS)**  
**Information for Clients**

**Researchers:**

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**Background and Purpose:**

We are asking you to be in the study because you want or have had an HIV antibody test. Public Health - Seattle & King County is working with the Centers for Disease Control and Prevention (CDC) to see if an experimental test, STARHS, improves HIV counseling and testing. STARHS may tell if a person infected with HIV got the infection in the 6 months before he/she was tested. Knowing when a person was infected with HIV may help the person and his / her health care providers decide the best treatment. It also may help identify the sexual and needle sharing partners of an HIV-positive person who need to be told about possible exposure to HIV. **We don't know how accurate this test is yet.** It is important to talk to your health care provider to see if you should have other tests to find out how long you have been infected.

STARHS uses the same blood taken for HIV testing. Usually no more blood needs to be taken. If only a small amount of blood was or is taken for the HIV test (such as by a finger stick) or if another body fluid was or is used (such as saliva), more blood would be needed.

This study is part of an Investigational New Drug (IND) application for biologic products because STARHS is different from the usual HIV test. The U.S. Food and Drug Administration (FDA) oversees research of new tests under an IND. We are studying the STARHS to see if it can accurately identify people who were recently infected with HIV-1.

**Procedures:**

If you agree to be in this study, this is what happens:

1. You tell the testing counselor that you want to be in the study.
2. If not previously done, your blood is tested for HIV antibodies using the routine method in the Public Health -- Seattle & King County lab.
3. If your blood shows that you are HIV-positive, the lab will use some of the remaining blood for STARHS. Usually you won't have to give more blood for this test. If the lab doesn't have enough blood for STARHS, we will ask to draw more. If you don't have HIV (you are HIV-negative), STARHS won't be done.
4. If STARHS is done, we will tell you the results when you next speak with a counselor, either when you return for your HIV test result and counseling session or at a time you arrange with your counselor. This adds about 5 minutes to the counseling session.
5. We will use the STARHS test result and information from your counseling session (your age, gender, race, risk factors for HIV, and whether you are taking medicine for HIV infection). For our study, we will only use this information to learn more about HIV in King County.
6. If your STARHS test result suggests that you have been infected recently, we will refer you to the University of Washington's Primary Infection Clinic, where you can get more tests and where you may be able to join studies that offer treatment of early infection. You may choose to go or not to go to the Primary Infection Clinic.

**Risks/Discomfort:**

1. The needle for your blood test may cause a temporary ache, bruise, or (rarely) infection.
2. The results from the STARHS test may not be accurate. Studies suggest that STARHS can identify most people who were infected with HIV within the last 6 months. **Your HIV-antibody test results won't change, whether STARHS is accurate or not.**
3. You may feel upset or uncomfortable thinking you may have been infected with HIV in the past 6 months. You may think certain recent partners gave you HIV. You may also feel concerned about giving HIV to recent partners. You may talk to the HIV testing counselor about your concerns, if you wish.
4. If you are injured as a result of being in this study, Public Health—Seattle & King County and CDC don't offer payment for injury.

**Benefits:**

1. If you are infected with HIV, the results of the STARHS test may suggest how recently you were infected. This may help you and your health care provider choose the best treatment.
2. STARHS test results may help you and your counselor or health care providers decide which sexual or needle-sharing partners need to be told that they may have been exposed to HIV.
3. Information from this study may help us improve HIV counseling and testing. We believe this study will help us understand more about the local HIV epidemic.

**Your Rights:**

You aren't required to take part in this study. You won't be penalized if you decide not to participate. You can still get the HIV-antibody test and your HIV test results. You can still take part in the counseling sessions. If you agree to let us test your blood using STARHS, you aren't required to get the results.

**Protecting Your Privacy:**

We will record your STARHS test results in our study computers. STARHS results won't be put in HIV testing records at Public Health-Seattle & King County. All study information will use your chart number for HIV testing.

State laws protect the privacy of medical records and HIV testing. We will keep your test results confidential and secure. We won't give the results of your HIV test or STARHS to anybody without your written permission. Only people working on the study will look at your STARHS results. All study files will be kept locked. All computers used for this study are protected by passwords. Study team members have signed an oath to protect confidentiality.

This study is part of an IND. The FDA has the right to look at clinical records of people who take part in our study to verify that it was done properly.

**Questions or Complaints:**

If you have questions about the study at any time, you can talk to your HIV testing counselor. You may also call the researchers listed above. If you have questions about your rights as a participant, you may call Maggie Frederick or Mike Garrick at 1-800-583-8488. They work for the Washington State Department of Health Human Research Review Board. The Review Board works to protect people who take part in studies.

**This information sheet is yours to keep.**